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EXAMINER	
HANDY, DWAYNE K	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/369,410	Applicant(s) Hehenberger et al.
	Examiner Dwayne K. Handy	Art Unit 1743

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on ______.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above, claim(s) ______ is/are withdrawn from consideration.

5) ☐ Claim(s) ______ is/are allowed.

6) ☒ Claim(s) *1-18* is/are rejected.

7) ☐ Claim(s) ______ is/are objected to.

8) ☐ Claims ______ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on ______ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on ______ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ______.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,7,11,*

18) ☐ Interview Summary (PTO-413) Paper No(s). ______

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1-6 and 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Sandstrom (5,631,171). Sandstrom teaches an instrument configured and arranged to detect a change in the thickness or refractive index of a substrate. The device is best shown in Figures 13-15 and described in column 39-42. From columns 39-40:

Referring to FIG. 13, there is shown a prior art method for detecting interaction of a light with a test surface. In the prior art, two polarizer were provided to allow such detection. Specifically, #1 corresponds to the white light source used in this prior art instrument. A standard halogen lamp is used to generate the polychromatic light. The light is incident on the polarizer at position #2, and is then linearly polarized. The linearly polarized light then impinges on the reference surface #3 which is at 70.degree. with respect to the test surface #4. The linearly polarized light is reflected from the reference surface (#3) as elliptically polarized light. The light then impinges the test surface (#4) and is reflected to the second polarizer at position #5. The interaction of the light with test surface (#4) inverts the s- and p- components of the elliptically polarized light. The polarizer at position #2 and #5 are matched and #5 is rotated 90.degree.

relative to #2. Light which is reflected from the test surface #4 which matches that reflected from the reference surface #3, will pass through polarizer #5 and be completely extinguished at the detector (#6). If there are any differences in the surface properties of surfaces #4 and #3, then some residual ellipticity will cause an increase in intensity to be measured at the detector #6.

Such an instrument which is useful for analysis of thin films and changes in film characteristics is the Comparison Ellipsometer described in U.S. Pat. Nos. 4,332,476, 4,655,595 and 4,647,207. The optical pathway of such instruments is shown in FIG. 13, as discussed above. This instrument can use a reference surface with a wedge of thicknesses across the surface. If thickness values are scribed onto the wedge, the thickness of a test surface may be determined relative to the wedge. The test surface thickness equals the wedge thickness at the point where light is extinguished at the detector.

The instrument operates on the basis of comparing the degree of elliptical polarization, caused by the reflection of plane polarized polychromatic light, between two surfaces. Incident polychromatic light is collimated and plane polarized. The polarized light is reflected at an oblique angle from the reference surface, which is a reflective substrate with similar or identical optical characteristics to that of the test piece. The reflected light is then elliptically polarized as a result of reflection. The elliptically polarized light then reflects from the test surface. The test surface and reference surface are arranged perpendicular to one another such that after reflection from the test surface, the light is once again plane polarized where the test and reference surfaces are optically identical. If their thickness and/or refractive indices are not identical, the light retains some elliptical character. The ellipticity is a function of the refractive index and the thickness differences. A second polarizer is then used to filter the light, and removes the plane polarized light corresponding to identical films. An increase in ellipticity will result in greater light transmission through the second polarizer. Thus, a change in thickness or refractive index is transformed into a change in light intensity which may then be measured using conventional techniques. By employing the Comparison Ellipsometer in this fashion, resolution to .+-.5.ANG. may be achieved. Unlike conventional ellipsometry, the Comparison Ellipsometer is designed to allow broad field measurements. This feature allows simultaneous measurement of the entire reaction zone. Therefore, measurement errors do not arise because of non-homogeneous binding or reaction patterns.

For the applications of this invention, a more useful reference surface is one which is uniform. When a test surface to be analyzed has all the components for colored signal generation for visual interpretation, the reference surface must also contain the optical thin film coating. This additional coating is not required for the instrumented analysis. To maximize the signal produced by a change in thickness or mass on the test surface, the reference standard should be approximately 50 to 100.ANG. thinner than the test surface, substrate, attachment layer, and receptive material. If these two surfaces are too closely matched, then a small change in thickness or mass will result in only a small increase in intensity relative to the original background intensity. The change in intensity for small thickness changes is dramatically increased when the background intensity is above a certain minimum or is sufficiently bright. With this reference surface all changes in thickness or mass cause a dramatic change in intensity of light measured by the detector relative to the test surface's initial reading. The change in intensity may reflect an increase in thickness or a decrease depending on the application, see Examples 8, 12, 13, 16, and 17. The instrumented reading protocols are given in Example 21.

For the analysis of specific binding reactions on a test surface, a number of modifications greatly improve the performance of the comparison Ellipsometer. The original design relied on the observer's eye for inspection of the surface.

Referring to FIGS. 14A and 14B, there are shown two devices in which no polarizer are provided, and in which a thin film can be analyzed either with a single photodiode, an array, or a CCD detector array, or with a reflectometer a photomultiplier detector.

The detector may be mounted where the eyepiece is located in the original instrument. It may also be mounted at 90.degree. to the side of the light path by incorporation of a partially silvered mirror or beamsplitter set at 45.degree. to reflect a portion of light to a detector, and the rest to the eyepiece for visual alignment of samples. If the mirror is inserted into the optical path, the spot intensity reaching the detector will be only a fraction of the light available. If the detector is directly in the optical pathway without a mirror, 100% of the sample intensity reaches the detector. When a beamsplitter and eyepiece are included in the apparatus, if care is not taken, stray light can be introduced which degrades the optical signal incident on the detector.

A photodiode array may be programmed to dedicate individual photodiodes to measure the intensity of reaction zones or spots, while other photodiode arrays measure the background, or control zones. Simultaneous measurement of the spot intensity and the background intensity allows each reading to be accurately corrected for test surface background.

Sandstrom, then, teaches an instrument which contains an illumination source, a detector, a positioning means, a controller, and a processing means. The Ellipsometer referred to by applicant and incorporated into the reference contains the control and processing means - a computer. The computer would also include memory means and microprocessing capabilities. The illumination source is capable of providing multiple wavelengths of light (col. 39, line 45) and capable of providing light at the angles required by applicant.

3. Claims 1, 4-7, 9-11, 12 and 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Howard, III et al. (6,180,409). Howard ('409) teaches a spectrophotometric apparatus. The device is best shown in Figures 1, 2, 5, and 6 and described in columns 3 and 4. From column 3:

(6) FIG. 2 is a perspective view of the interior mechanical structure of the spectrophotometer 10. Referring to FIG. 2, the spectrophotometer 10 includes a light emitting apparatus 30, which may be provided in the form of five light-emitting diodes (LEDs) 30a-30e, which may be in the form of narrow angle, high output LEDs commercially available from Hewlett Packard. The LEDs 30a-30e may be spaced apart so that each of them illuminates a separate portion of the reagent strip receiving area 12. The spectrophotometer 10 includes a detecting apparatus 32, which may be in the form of four light detectors 32a-32d, each of which is disposed between two of the LEDs 30a-30e. The detectors 32a-32d are positioned so that they detect light which is received from portions of the receiving area 12 which are illuminated by the LEDs 30a-30e.

(7) As shown in the left-hand portion of FIG. 2, the spectrophotometer 10 includes a pivot arm 34 having a central portion which is connected to a rotatable shaft 36, which is controllably driven by a motor (not shown). The end of the pivot arm 34 is slidably disposed in a vertical shaft formed in the back of a transfer arm support member 38 to which the transfer arm 18 (FIG. 1) is connected. The transfer arm support member 38, which has a receptacle 40 in which an end of the transfer arm 18 is disposed, is slidably supported by a horizontally disposed cylindrical rod 42. The horizontal position and movement of the transfer arm 18 is controlled by selectively causing the pivot arm 34 to rotate about the central shaft 36 to change the lateral position of the end of the pivot arm 34, and thus the lateral position of the transfer arm support member 38.

(8) As shown in the right-hand portion of FIG. 2, the spectrophotometer 10 has a movable carriage 50 that is fixed to one side of a positioning belt 52 supported by a pair of toothed gears 54, 56. The gear 56 is fixed to a rotatable drive shaft (not shown) that is controllably driven by a motor 58 (FIG. 6) to precisely move and position the movable carriage 50 in a direction parallel to the length of the reagent strip 14 (FIG. 1). Although a positioning system in the form of gears 54, 56 and belt 52 is shown, other types of positioning systems could be utilized, such as one or more round gears which mate with a linear gear fixed to the readheads 60, 62, or any type of positioning system adapted to adjust the linear position of a device.

(9) The movable carriage 50 has a pair of readheads 60, 62. The readhead 60 includes a light source 64 (FIG. 6), which may be provided in the form of an incandescent lamp, for example, and a detector 66, which may be provided in the form of four light detectors 66a-66d, each of which is adapted to detect light of a different wavelength, such as red, blue, green and infrared light, for example. The readhead 62 includes a light source 68 (FIG. 6), which may be provided in the form of an incandescent lamp, and a detector 70, which may be provided in the form of four light detectors 70a-70d, each of which is also adapted to detect light of a different wavelength. Although the readheads 60, 62 could be designed as disclosed in U.S. Pat. No. 5,661,563 to Howard, et al., which is incorporated by reference herein, no

particular design of the readheads 60, 62 is considered necessary to the invention. The light sources 64, 68 could be other than incandescent light sources, and the detectors 66, 70 could be designed to detect light of only a single wavelength.

Howard ('409), then, teaches an instrument which contains an illumiation source, a detector, a positioning means, a controller, and a processing means. Howard ('409) teaches calibration using data stored in a processing means is cited in column 7. The computer also includes memory means, microprocessing capabilities, and a display for showing results.

4. Claims 1, 4-10, 12 and 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Bolea (6,063,591). Bolea (6,063,591) teaches a system for measuring the efficacy of a sterilization cycle. The system uses a biological indicator which exhibits fluorescence in response to optical excitation. The fluorescence is then read by the system and compared to a previous reading. The system is best shown in Figure 1A and described in columns 3 and 4:

(2) FIG. 1A is a block diagram of a biological indicator reading system 10 (system 10) in accordance with one aspect of the present invention. System 10 includes electro-optical excitation module 12, electro-optical sensing module 14, reference module 15, controller electronics 16, operator interface 18, optional scope 20, heater servo 22, empty chamber detector 23 and incubator and optical integration cavity 24 (incubator 24) which includes incubator module 25 and optical integration cavity 36 formed therein. System 10 also illustrates a biological sterilization indicator 26 (BI 26) with antirotational feature on its cap 28 seated within incubator 24.

(3) In the preferred embodiment, BI 26 is a biological sterilization indicator commercially available from the Minnesota Mining and Manufacturing Company of St. Paul, Minn., under the trade name, 3M Attest, models 1291 or 1292. BI 26 includes cap 28, vial 30 and various contents (not shown). BI 26 evidences the presence of a viable microorganism (such as spores) by the production of fluorescence within vial 30 after incubation in incubator 24. This is preferably accomplished by utilizing a non-fluorescent substrate (such as 4-methylumbelliferyl-alpha-D-glucoside) in vial 30 and converting that non-fluorescent substrate to a fluorescent product by spore-associated enzyme activity. The spore-associated enzyme is preferably alpha-D-glucosidase, which is one of the enzymes involved in the growth of the spore within vial 30.

(4) In order to take a fluorescence reading from BI 26, electro-optical excitation module 12 provides optical excitation to the fluorescent substances in vial 30 and to reference module 15. Electro-optical excitation module 12 preferably includes a flash mechanism 32 and a filter 34. Flash mechanism 32, in one preferred embodiment, is a flash tube which emits a broadband light pulse (as approximately a 100 .mu.s pulse) which is rich in the near ultra-violet range of wavelengths. Alternatively, a cold cathode flourescent lamp may be used instead of the flash tube. This is a continuous wave type device. A commercially available example of such a device is the JKL BF350-UV351 available from JKL Corp. of California, U.S.A.

(5) Filter 34 is preferably an absorptive color glass filter which exhibits low autofluorescence and passes selected wavelengths. A suitable filter is a Schott bg 39, ug 11 filter which is available from Schott Glass Technologies, Inc. of Duryea, Pa.

(6) The light is passed through filter 34 and impinges on vial 30 and reference module 15. Reference module 15 preferably includes filter 35 and reference optical sensor 37. Filter 35 is preferably a filter, or set of filters, which is chosen to pass the excitation energy which passes through filter 34. Filter 35 passes this energy to reference optical sensor 37. A suitable filter is a Schott bg 39, ug 11 filter which is available from Schott Glass Technologies, Inc. of Duryea, Pa.

(7) Reference optical sensor 37 senses the energy passing through filter 35 and provides a reference signal to controller electronics 16 which is indicative of the energy passing through filter 35. Thus, the reference signal provided to controller electronic 16 by reference optical sensor 37 is indicative of the intensity of the flash emitted by flash mechanism 32.

(8) The light which is passed through filter 34 and impinges on vial 30 excites the fluorescence material in vial 30. The fluorescence emitted from vial 30 is preferably collected by an integration cavity 36 which is preferably a geometric reflective cavity (such as parabola or sphere shaped) arranged about vial 30 to collect (or integrate) the fluorescence emitted from vial 30 and to direct that fluorescence to electro-optical sensing module 14.

(9) Electro-optical sensing module 14 includes filter 38 and optical sensor 40. Filter 38 is preferably a filter, or a set of filters, which is chosen to reject surface reflection from the surface of vial 30 when the flash impinges on the surface of vial 30. A suitable filter blocks light in approximately the 350 nm wavelength range and passes light in approximately the 450 nm wavelength range. Any suitable filtering can be used which tends to reduce interference between the excitation energy from flash mechanism 32 and the emission energy from vial 30. This filter acts to pass the emission wavelengths which are indicative of fluorescence in vial 30. One suitable filter used as filter 38 is provided by Schott Glass Technologies, Inc. as a Schott bg 39, kv 408 filter. The output of filter 38 is provided to optical sensor 40 which is preferably a blue enhanced photodiode which enhances the sensitivity of the photodiode in the 400-450 nm wavelength range. One suitable optical sensor 40 is provided by Burr Brown Corporation of Tucson, Ariz. under the trade name OPT 301.

(10) The output of optical sensor 40 is provided to controller electronics 16. In the preferred embodiment, controller electronics 16 is a microprocessor based controller which includes associated memory and

timing circuitry and amplifiers and other suitable conditioning circuitry for receiving the outputs from optical sensors 37 and 40 and providing them as conditioned signals indicative of the intensity of flash mechanism 32 and of the fluorescent activity in vial 30, respectively. Controller electronics 16 also preferably includes connection to a suitable operator interface 18. In the preferred embodiment, operator interface 18 includes a CRT and keyboard, or a membrane keypad input, a touch screen input or any other suitable operator interface device. Controller electronics 16 may be connected to optional scope 20 which is a commercially available oscilloscope used to provide a display indicative of the signal received from the optical sensor 40. Finally, controller electronics 16 is also preferably coupled to heater servo 22 and empty chamber indicator 23.

Bolea, then, teaches an instrument which contains an illumiation source, a detector, a positioning means, a controller, and a processing means. Bolea cites various types of refernce data and calibration steps in column 9-12 in discussing how the device uses baseline readings of fluorescence in determining the fluorescence readings. Use of "controller electronics" in operating the device is taugh in these columns as well.

Final note on 102 rejections

In advance of applicant's response, the Examiner wishes to comment on the 102 rejections as a whole. In the instant claim 1, applicant has claimed "An apparatus for reading a chemical indicator for monitoring a sterilization process, the chemical indicator comprising a substantially flat surface and a sterilizing agent sensitive ink

Based on the current structure of the claim, applicant appears to be attempting to place a limitation on the device that is based upon *what it will examine* - the chemical indicator. . The Examiner reminds applicant that this phrase in the preamble of the claim carries no patentable

weight when examining the claims against the prior art. Nor would it carry any patentable weight if located outside the preamble as it goes to an intended use of the device. To meet the limitations of claim 1, the Examiner merely needs to provide prior art which contains an illumiation source, a detector, a positioning means, a controller, and a processing means. The Examiner believes he has done so.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Howard III (5,945,341) teaches a system for the optical identification of coding on a test strip. Kirckof (6,488,890), Kirckof et al. (6,485,978), Ignacio et al. (6,440,744) and Amhof et al. (6,238,623) teach sterilization indicators and methods of using them. Jacobs et al. (6,454,874) recite a method for detecting the cleanliness of a medial device which includes optical analysis. Ryder et al. (4,657, 870) teach an optical system for viewing a receptacle which indicates sterility.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.

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dkh

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